NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

REMBRANDT DIAGNOSTICS, LP,

Plaintiff-Appellant

v.

ALERE, INC., ALERE TOXICOLOGY SERVICES, INC., INNOVACON, INC., INSTANT TECHNOLOGIES, INC.,

Defendants-Cross-Appellants

2019-1595, 2019-1648

Appeals from the United States District Court for the Southern District of California in No. 3:16-cv-00698-CAB-NLS, Judge Cathy Ann Bencivengo.

Decided: April 10, 2020

JOSEPH F. JENNINGS, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA, argued for plaintiff-appellant. Also represented by JARED C. BUNKER; ASHLEY C. MORALES, San Diego, CA.

JASON M. WILCOX, Kirkland & Ellis LLP, Washington, DC, argued for defendants-cross-appellants. Also

represented by Hannah Lauren Bedard, John C. O'Quinn; James F. Hurst, Amanda J. Hollis, Chicago, IL.

Before WALLACH, MAYER, and STOLL, Circuit Judges. STOLL, Circuit Judge.

These appeals arise from an action for patent infringement. Rembrandt Diagnostics, LP sued Alere, Inc., Alere Toxicology Services, Inc., Innovacon, Inc., and Instant Technologies, Inc. (collectively, "Alere"), alleging that Alere's products infringe claims 3-6 and 10 of Rembrandt's U.S. Patent No. 6,548,019, directed to devices for collecting and assaying biological fluid samples. Prior to trial, Rembrandt stipulated to a judgment of noninfringement of claims 3-6 in light of the district court's construction of a disputed claim limitation. During the trial, the district court construed another disputed claim limitation, and the jury rendered a verdict of noninfringement and no invalidity as to claim 10. Rembrandt now challenges the district court's constructions of the two disputed claim limitations. Alere cross-appeals, requesting that this court order a new trial on validity of claim 10 if it remands for a new trial on infringement of that claim. Because we conclude that the intrinsic evidence supports Rembrandt's proposed constructions, we vacate the district court's judgments and remand for further proceedings as to claims 3–6 and a new trial on both infringement and validity for claim 10.

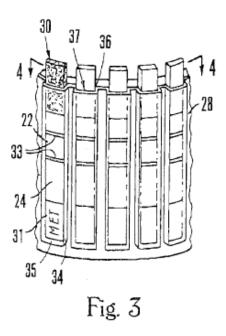
# BACKGROUND

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The '019 patent "relates to immunoassay devices and methods for collection and assaying of biological fluids, particularly urine." '019 patent col. 1 ll. 15–17; see also id. at Abstract. In particular, the patent discloses a "means for controlling assay sample fluid flow through an assay test strip," wherein "fluid flow control is accomplished by

placing the assay test strip within a flow control channel in which the ambient pressure within the flow control channel is maintained in substantial equilibrium with the ambient pressure outside the flow control channel." *Id.* at col. 1 ll. 40–47. "By avoiding the formation of a pressure gradient within the flow control channel," the device of the '019 patent minimizes "the risk of oversaturation of the test strip on introduction into an assay sample fluid." *Id.* at col. 1 ll. 48–55.

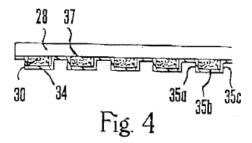
Figure 3 illustrates a front view of the preferred embodiment of the '019 patent. *Id.* at col. 2 ll. 18–19.



*Id.* Fig. 3. In this embodiment, the sample loading zone (30) of the assay test strip (22) partially extends beyond the opening of the flow control channel (34). The specification explains that "[a]ssay sample fluid control in this embodiment . . . is accomplished by disposing assay test strip 22 within a flow control channel." *Id.* at col. 5 ll. 57–59.

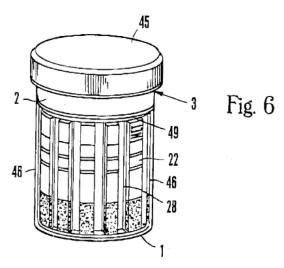
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Figure 4 illustrates a cross-section of the top portion of Figure 3. *Id.* at col. 2 ll. 20–21.



*Id.* Fig. 4. The flow control channel "has five liquid impervious walls 35, 35A, 35B, 35C and backing 28, and one liquid pervious side consisting of an opening 36 through which sample loading zone 30 of assay test strip 22 protrudes." *Id.* at col. 6 ll. 11–16; *see also id.* at col. 6 ll. 38–40 ("Open end 36 has an opening 37 which is loosely fitted around test strip 22, whose sample loading zone 30 protrudes beyond opening 37.").

Figure 6 shows a "front view of an assay sample fluid collection device of the invention, into which is inserted the dipstick assay means of" Figures 3 and 4. *Id.* at col. 2 ll. 24–27.



*Id.* Fig. 6.

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Claim 1, the only independent claim of the '019 patent, recites the two disputed claim limitations:

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- 1. A device for collecting and assaying a sample of biological fluid, the device comprising:
- (a) a flow control channel defined by at least one liquid pervious side joined to liquid impervious sides, wherein the internal dimensions of the flow control channel are sufficient to permit placement therein of an assay test strip;
- (b) an assay test strip within the flow control channel, wherein the assay test strip has a sample loading zone therein, and wherein further the assay test strip is disposed within the flow control channel so the sample fluid contacts the sample loading zone at a liquid pervious side of the flow control channel; and
- (c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth;

wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container so that the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel without migration through an intermediate structure, and wherein entry of fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel, thereby eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel.

*Id.* at col. 8 l. 42–col. 9 l. 2 (emphases added).

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The claims at issue on appeal are dependent claims 3–6 and 10. Claim 10 requires that "all of the assay test strips" in the device "are disposed in a single flow control channel." *Id.* at col. 10 ll. 5–6. None of the limitations of claims 3–6 or 10 is in dispute.

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Rembrandt accused four Alere urine test cup products of infringing claims 3–6 of the '019 patent: the iCup DX Pro, AmediCheck, DrugSmart, and UScreen.¹ Rembrandt alleged that these four products were copies of the preferred embodiment illustrated in Figures 3, 4, and 6 of the '019 patent. Rembrandt also accused a fifth Alere urine test cup product—the iCup A.D.—of infringing claim 10. Rembrandt alleged that unlike the other four accused products, the assay test strips of the iCup A.D. are disposed in a single flow control channel, as required by claim 10, and do not protrude from the end of the channel.

As noted above, there are two claim limitations at issue on appeal: "the assay test strip is disposed within the flow control channel" in claim 1 and the claims that depend from claim 1 (the "disposed within" limitation); and "entry of fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel" in

In a parallel inter parties review proceeding, Rembrandt disclaimed claims 1, 9, and 11–15 of the '019 patent, leaving only claims 2–5 in dispute. Because the Board did not institute review of all claims and grounds in the IPR petition, this court vacated the Board's patentability determinations as to claims 2–5, and remanded for the Board to review all claims and grounds included in the petition pursuant to SAS Institute, Inc. v. Iancu, 138 S. Ct. 1348 (2018). Alere, Inc. v. Rembrandt Diagnostics, LP, 791 F. App'x 173, 178 (Fed. Cir. 2019).

claim 1 and the claims that depend from claim 1 (the "equivalent to" limitation).

Prior to trial, the district court construed the "disposed within" limitation to require that "the assay test strip is disposed entirely within the flow control channel." Rembrandt Diagnostics, L.P. v. Innovacon, Inc., No. 16–698, 2017 WL 6059129, at \*4 (S.D. Cal. Dec. 7, 2017) (Claim Construction Op.) (emphasis added). Rembrandt had proposed that the limitation should be "accorded its plain and ordinary meaning" and that, to the extent the court construed the limitation, it should mean "the assay test strip is placed or arranged within the flow control channel." J.A. 2932. The district court rejected this proposed construction, which would allow the assay test strip to "protrude at the pervious end such that the sample loading zone of the strip extends beyond the channel in the manner described in the specification and depicted in Figure 3." Claim Construction Op., 2017 WL 6059129, at \*3 (citations omitted). While acknowledging that a "claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct," the district court nonetheless determined that the "unambiguous" claim language and the prosecution history "result[ed] in the exclusion of a preferred embodiment that teaches the loading zone can protrude from the channel." Id. at \*4 (citations omitted).

Following the district court's construction of the "disposed within" limitation, Rembrandt stipulated to the district court's entry of judgment that none of accused products iCup DX Pro, AmediCheck, DrugSmart, or UScreen infringed claims 3–6 of the '019 patent "because the test strips in such products are not 'disposed entirely within the flow control channel." Pretrial Order at 3, Rembrandt Diagnostics, LP v. Alere, Inc., No. 16–698 (S.D. Cal. Nov. 19, 2018), ECF No. 312.

The case then proceeded to a jury trial solely concerning the validity of claim 10 and the iCup A.D. product's alleged infringement thereof. During the trial, the district court construed the "equivalent to" limitation in claim 1 to mean "equal to." J.A. 10941 at 434:12–17. The district court rejected Rembrandt's proposed construction of the disputed limitation to mean "in equilibrium with." The district court thereafter instructed the jury that "equivalent to" was defined as "equal to." The jury found that the iCup A.D. product did not infringe claim 10, and that claim 10 was not invalid for anticipation or obviousness.

Rembrandt and Alere appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

### DISCUSSION

We start by addressing Rembrandt's challenge to the district court's constructions of the two disputed claim limitations: the "disposed within" limitation and the "equivalent to" limitation. We then turn to Alere's cross-appeal, in which it contends that if this court remands for a new trial on infringement for claim 10, it should order a new trial on validity as well.

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Claim construction based on the intrinsic evidence is a question of law that this court reviews de novo. *Trustees of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1362 (Fed. Cir. 2016). "The construction of claim terms based on the claim language, the specification, and the prosecution history are legal determinations." *Id.* The two claim construction disputes in this case present close questions. Based on our review of the claim language, specification, and prosecution history, however, we conclude that the district court erred in construing the disputed claim limitations.

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We consider first Rembrandt's challenge to the district court's construction of "disposed within." At the outset, we recognize that the language of claim 1 is ambiguous. The parties' arguments focus on two specific phrases in claim 1. First, the device of claim 1 comprises an "assay test strip" that is "disposed within the flow control channel so the sample fluid *contacts* the sample loading zone *at* a liquid pervious side of the flow control channel." '019 patent col. 8 ll. 42–54 (emphases added). Second, the device is arranged in such a way that the "assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip *by entry through* a liquid pervious side of the flow control channel without migration through an intermediate structure." *Id.* at col. 8 ll. 57–64 (emphasis added).

Both parties present reasonable arguments about how the disputed limitation should be understood based on this claim language. Alere contends that the district court's construction is correct because if the test strip were to "protrude" from the flow control channel, the sample fluid would contact the strip before the fluid reaches the channel. Thus, according to Alere, the fluid would not "contact" the test strip's loading zone "at" the liquid pervious side of the channel, as required by claim 1; instead, the contact would happen on the protruding portion of the strip outside of the channel. In addition, the fluid would not be "delivered" to the test strip's loading zone "by entry through" the liquid pervious side of the channel, as also required by claim 1.

Rembrandt's broader construction—which encompasses devices with protruding test strips—also finds support in the claim language. Rembrandt contends that claim 1 does not require that the sample fluid contact the test strip's loading zone "first and only precisely at the opening of the flow control channel and nowhere else."

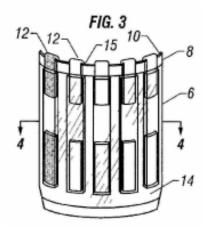
Appellant's Resp. Br. 5 (emphasis in original). In Rembrandt's view, "at" is not limited to "the singular spot of entry to the flow control channel" and, in fact, such a construction "would exclude a device in which the test strip is entirely within the flow control channel but does not extend to being flush with it." *Id.* Rembrandt also contends that claim 1 does not require that the "fluid be delivered to the test strip 'only' by entry through the channel opening and nowhere else." *Id.* In sum, the claim language does not definitively support one construction over the other.

We turn next to the specification, which "is the single best guide to the meaning of a disputed term." Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). There is no dispute that the district court's construction excludes the preferred embodiment of the '019 patent, as depicted in Figures 3 and 4. Claim Construction Op., 2017 WL 6059129, at \*4. By contrast, Rembrandt's proposed construction encompasses the preferred embodiment. There is also no dispute that, in describing the preferred embodiment, the specification uses nearly identical language as the disputed claim language. Compare '019 patent col. 8 ll. 51–52 ("the assay test strip is disposed within the flow control channel" (emphasis added)), with id. at col. 5 ll. 57-59 ("Assay sample fluid control in this embodiment of the invention is accomplished by disposing assay test strip 22 within a flow control channel ...." (emphases added)).

Turning next to the prosecution history, we are not persuaded that the prosecution history includes a clear and unmistakable surrender of claims directed to a preferred embodiment in which test strips protrude. Nor are we persuaded that any of the inventors' statements otherwise require a claim construction that would omit a preferred embodiment.

Claim 1 was initially drafted to recite a method comprising the step of "disposing an assay test strip within the flow control channel," wherein the "assay test strip is disposed within the flow control channel so the sample loading zone is *flush with*, or protrudes from, a liquid pervious side of the flow control channel." J.A. 11517 (emphasis added). The Patent Office rejected claim 1 as anticipated by, and for obviousness-type double patenting over, related U.S. Patent Application No. 09/192,969. The '969 application issued as U.S. Patent No. 6,379,620 (Tydings).

Tydings shares an inventor with the '019 patent and discloses and claims a device that Rembrandt refers to as the inventors' "first generation drug test cup design." Appellant's Br. 8. Like the device recited in claim 1 of the '019 patent, Tydings discloses a device that uses assay test strips, as illustrated in Figure 3 of Tydings:



Tydings Fig. 3. The prior art Tydings device is also depicted in Figures 1 and 2 of the '019 patent.

The Tydings device uses a wicking material, such as filter paper or fiber glass, which "extends substantially the full length of the backing" of the cup. *Id.* at col. 2 ll. 40–45. As shown in Figure 3, the "top portion of the reagent strip 12 is bent over the top edge 15 of the backing 8 and overlapped onto the wicking paper 10." Id. at col. 2 ll. 65–67.

Urine "wicks up the wicking material 10 until it reaches the overlapped portions of the assay strips 12," and then "wicks over the top edge of the backing 8 and down the assay strips 12." *Id.* at col. 3 ll. 25–28. "The urine wicking down the assay strips 12 will react with the chemical agents" on the strip and "will give positive, negative or inconclusive test results." *Id.* at col. 3 ll. 28–31.

In its response to the examiner's office action, the applicants distinguished Tydings on the ground that the claimed invention:

provides a flow control channel whereby the sample is delivered *directly* to the sample loading zone 30 of assay strip 22 through a liquid pervious side 36 (as opposed to having the fluid migrate through an intermediate structure, such as wicking material 10 of FIGS. 1 and 2 [the '969 device] . . . ).

J.A. 11613 (underlining omitted). In addition, the applicants amended claim 1 to recite a device and added the requirement that "the assay sample fluid, when added to the container, is *delivered directly* to the sample loading zone through a liquid pervious side of the flow control channel." J.A. 11601 (emphasis added).

The patent examiner was not convinced and maintained the rejections based on Tydings. The applicants thereafter amended claim 1 to recite, in relevant part, that "the assay test strip is disposed within the flow control channel so the sample fluid *contacts* the sample loading zone *at* a liquid pervious side of the flow control channel." J.A. 11674 (emphases added). At the same time, the applicants removed the requirement that the test strip's sample loading zone "is flush with, or protrudes from," a liquid pervious side of the channel. *Id.* The applicants further amended the claim to recite that fluid is "delivered directly to the sample loading zone of the assay test strip through a liquid pervious side of the flow control channel *without* 

migration through an intermediate structure." Id. (emphasis added). The applicants reiterated to the examiner that, in contrast to the Tydings device, the claimed invention did not use an intermediate structure.

Shortly thereafter, the applicants further amended claim 1 to recite that "the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel without migration through an intermediate structure," and removed the requirement that the fluid is delivered "directly" to the loading zone. J.A. 11688 (emphasis added). The applicants explained that their invention "improves upon previous devices by preventing the flooding of test strips by constructing a flow channel around the strips," and that the liquid pervious side of the channel "limit[s] the rate at which sample will flow into the channel to contact the sample loading zone on the assay strips." J.A. 11686 (emphases added).

Alere's argument that the applicants' amendments during prosecution support a narrower construction has some merit. Ultimately, however, we disagree with Alere and the district court that the applicants narrowed the scope of claim 1 during prosecution to cover only devices with test strips that are disposed "entirely" within the flow control channel. In particular, the applicants did not merely remove "protrudes from" in claim 1; rather, they removed "is flush with, or protrudes from." J.A. 11674. In addition, the applicants never distinguished the Tydings device (or any other prior art device) on the ground that the claimed test strips cannot protrude beyond the channel. Instead, the applicants expressly distinguished the Tydings device on the basis that Tydings used an intermediate structure, and amended the claims to exclude the use of such intermediate structure. And although the additions of the "by entry" and "contact . . . at" language in claim 1 were made in conjunction with, or shortly after, removal of the "flush with, or protrudes from" language, these additions were also made when the applicants amended claim 1 to exclude the use of an intermediate structure. Alere emphasizes that claim 1 was amended to exclude the protruding strips embodiment while still covering the flush strips embodiment based on the added language that "the sample fluid contacts the sample loading zone at a liquid pervious side of the flow control channel." But, as we have already discussed, this language is at best ambiguous and does not require a construction that the strips must be contacted only at a particular location.

Contrary to the district court's suggestion, Elekta Instrument S.A. v. O.U.R. Scientific International, Inc., 214 F.3d 1302 (Fed. Cir. 2000), does not "compel[] adopting [a] construction excluding [the preferred] embodiment" of protruding strips based on the applicants' amendments in this case. Claim Construction Op., 2017 WL 6059129, at \*4 (citing *Elekta*, 214 F.3d at 1308). In *Elekta*, the claim at issue expressly required gamma units with radiation sources "only within a zone extending between latitudes 30°-45°." 214 F.3d at 1306. The preferred embodiment disclosed sources between 0°-45°, and the district court construed the claim to cover sources beginning at 0° and extending to a point between 30°-45°. Id. at 1306-07. We held that the district court's construction was inconsistent with the "unambiguous" claim language, which "controls over any contradictory language in the written description." Id. at 1308. In light of the unambiguous claim language and the prosecution history—in which the applicants expressly limited their invention to sources located exclusively between 30° and 45°—this court held that this was the "rare case" in which the construction must exclude the preferred embodiment. Id. Here, in contrast, neither the claim language nor the prosecution history

demonstrates that claim 1 is "susceptible of only one reasonable construction." *Id.* 

We have considered Alere's other arguments, but we do not find them persuasive. Although Rembrandt's challenge presents a close issue, we conclude that the claim language, specification, and prosecution history are more aligned with a broader construction that would not exclude the preferred embodiment. Accordingly, we construe the "disposed within" limitation to mean "the assay test strip is placed or arranged within the flow control channel."

В

We next consider Rembrandt's challenge to the district court's construction of the "equivalent to" limitation, along with the district court's jury instruction based thereon. "An erroneous instruction regarding claim interpretation that affects the jury's decision on infringement is grounds for a new trial." *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1373 (Fed. Cir. 2002). "A party seeking to alter a judgment based on erroneous jury instructions must establish that 'those instructions were legally erroneous,' and that 'the errors had prejudicial effect." *Id.* (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1281 (Fed. Cir. 2000)). Whether a jury instruction is legally erroneous is a question of law. *Id.* (citing *Brooktree* 

<sup>&</sup>lt;sup>2</sup> Alere cites *North American Container*, *Inc. v. Plastipak Packaging*, *Inc.*, 415 F.3d 1335 (Fed. Cir. 2005) and *Uship Intellectual Properties*, *LLC v. United States*, 714 F.3d 1311 (Fed. Cir. 2013), for the proposition that claim limitations may be construed to exclude a preferred embodiment if the prosecution history compels that result. Unlike this case, each of those cases involved narrowing amendments or remarks that clearly removed the preferred embodiments from the claim scope.

Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1570 (Fed. Cir. 1992)).

This claim construction issue also presents a close question. Based on our review of the claim language, specification, and prosecution history, however, we conclude that Rembrandt's proposed construction of the "equivalent to" limitation to mean "in equilibrium with" is more consistent with the intrinsic record than the construction adopted by the district court. We also conclude that Rembrandt has demonstrated that the jury instruction was erroneous and prejudicial.

The plain claim language suggests a broader meaning of "equivalent to" than "equal to." Claim 1 recites, in relevant part, that the "entry of fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel, thereby eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel." '019 patent col. 8 l. 64-col. 9 l. 2 (emphasis added). Similar to the oft-used claim term "substantially," we consider "equivalent," as used in claim 1, to be a term of degree that does not require mathematical precision. See Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1367 (Fed. Cir. 2001) ("[T]he term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter." (quoting Pall Corp. v. Micron Seps., 66 F.3d 1211, 1217 (Fed. Cir. 1995))). Indeed, as Rembrandt correctly observes, the patent law doctrine of equivalents refers to the legal comparison of two elements that are, in fact, different, which supports that "equivalent" is not limited to "equal." If the applicants meant "equal," they would have used the word "equal" rather than the broader word "equivalent." Claim 1 neither uses the term "equal" nor refers to a numerical measurement, numerical comparison between pressures, or even the pressure unit of measurement—pascals.

The specification also supports a broader interpretation of the claim language. The specification repeatedly uses terms other than "equal" to describe achieving the claimed result of "eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel." For example, the specification teaches:

By maintaining *substantial ambient pressure equilibrium* about the flow control channel, no pressure gradient is allowed to form along which fluid outside the flow control channel will flow into the flow control channel.

Id. at col. 6 ll. 28–31 (emphasis added); see also id. at Abstract, col. 1 ll. 42–47, col. 5 ll. 57–64, col. 5 l. 64–col. 6 l. 2, col. 6 ll. 23–31, 47–51 (referring to "equilibrium" or "substantial equilibrium"). Like claim 1, the specification never uses the term "equal" when discussing air pressure, nor does it mention pascals, pressure tests, or numerical measurements. Thus, the specification further supports Rembrandt's construction, which "captures immaterial and insubstantial differences in the two pressures," Appellant's Br. 56, over a construction that requires mathematical equality.

We understand the district court's view that "equivalent" could mean "equal" given the applicants' statements during prosecution about the pressures inside and outside the channel being "equalized." Specifically, the applicants argued that "the liquid pervious side of the channel serves as a pressure equalizer," J.A. 11611 (emphasis added), and that the "present invention utilizes equalized pressure," J.A. 11650 (emphasis added). But even "equalized pressure" does not mean the pressures are mathematically, precisely equal. For instance, when explaining the "ambient pressure" limitation and distinguishing the Tydings device, the applicants described their invention as using a flow control channel to create a "pressure equilibrium." J.A. 11672; see also J.A. 11611 ("The present invention

improves upon previous devices by preventing the flooding of test strips by constructing a flow channel so the air pressure within it stays in *substantial equilibrium* with the air pressure outside of it." (emphasis added)).

We have considered Alere's other arguments, but we do not find them persuasive. We conclude that the district court's construction imposes a mathematical or numerical rigor of exactness that is not supported by the intrinsic evidence. Accordingly, we construe the "equivalent to" limitation to mean "in equilibrium with." We also hold that the jury instruction that included the district court's construction was prejudicial and requires the verdict of noninfringement of claim 10 to be set aside.

II

We next turn to the issue raised in Alere's cross-appeal. Because we have determined that the district court's construction of the "equivalent to" limitation was erroneous, we conclude that a new trial will be necessary to determine whether the asserted prior art anticipates or renders obvious claim 10 under the correct construction of the "equivalent to" limitation.

"The Federal Rules of Civil Procedure allow the courts to grant partial new trials so long as the issues are 'distinct and separable." Commil USA, LLC v. Cisco Sys., Inc., 720 F.3d 1361, 1371 (Fed. Cir. 2013) (citing Fed. R. Civ. P. 59), vacated in part, 575 U.S. 632 (2015). "A court's authority to grant a partial new trial is likewise constrained by the Seventh Amendment." Id. (citing Gasoline Prod. Co. v. Champlin Refining Co., 283 U.S. 494, 500 (1931)). "Where the practice permits a partial new trial, it may not properly be resorted to unless it clearly appears that the issue to be retried is so distinct and separable from the others that a trial of it alone may be had without injustice." Id. (quoting Gasoline Prod., 283 U.S. at 500). "A partial new trial should not be granted where the issues to be retried are 'so interwoven' with other issues in the

case 'that the former cannot be submitted to the jury independently of the latter without confusion and uncertainty." *Id.* (quoting *Gasoline Prod.*, 283 U.S. at 500).

It is true, as Rembrandt asserts, that infringement and validity are distinct issues and that this court previously stated that it "routinely orders a partial new trial on infringement, while upholding an earlier verdict on validity." Commil, 720 F.3d at 1371 (first citing Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 381 F.3d 1371, 1374 (Fed. Cir. 2004); then citing Comaper Corp. v. Antec, Inc., 596 F.3d 1343, 1354–55 (Fed. Cir. 2010)). Rembrandt contends that the correct construction of "equivalent to" was "not material to the jury's rejecting Alere's challenge to the validity of claim 10" because the evidence showed that the asserted prior art reference "failed to meet the 'equivalent to' limitation even under the correct construction." Appellant's Resp. Br. 33.

The testimony of Alere's expert, however, demonstrates that the infringement and validity issues are intertwined. See, e.g., J.A. 11077-78 at 570:5-571:9; J.A. 11117 at 610:18-20. Alere would suffer an injustice if it were not permitted to challenge the validity of claim 10 under Rembrandt's proposed construction in a new trial if Rembrandt has another opportunity to prove infringement. See Commil, 720 F.3d at 1371. Although Rembrandt cites testimony by its expert that the asserted prior art reference does not disclose "a flow control channel and flow control capability as required by claim 10" to show that a new trial on invalidity is unnecessary, Appellant's Resp. Br. 36 (citing J.A. 11130-32 at 623:25-625:9), Alere identifies contrary testimony of both parties' experts that the reference does, in fact, disclose all the elements of claim 10. Cross-Appellant's Resp. Br. 4–6 (citing J.A. 11068 at 561:4–21; J.A. 11078–81 at 571:10–574:4; J.A. 11138–41 at 631:13– 634:15). Thus, a reasonable jury could find based on the evidence that the asserted prior art teaches the "equivalent to" limitation under the correct construction.

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Accordingly, we remand for a new trial on both infringement and validity of claim 10 under the correct construction of the "equivalent to" limitation.

## CONCLUSION

For the foregoing reasons, we vacate the district court's judgment of noninfringement as to claims 3–6 and remand for further proceedings under the proper construction of the "disposed within" limitation. We also vacate the district court's judgment of noninfringement and validity as to claim 10 and remand for a new trial on the issues of infringement and validity of that claim under the proper construction of the "equivalent to" limitation.

# VACATED AND REMANDED

Costs

Costs to Appellant.